OCT 3 0 2003

Quantimetrix Corporation 2005 Manhattan Beach Boulevard
Redondo Beach, CA 90278-1205

TEL (800) 624-8380 or (310) 536-0006
FAX (800) 845-1834 or (310) 536-9977

## 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K032791

| | |
|---|---|
| **Proprietary Name:** | GlycoHemosure |
| **Common Name:** | Calibrators/Controls |
| **Classification Name:** | Glycosylated Hemoglobin Assay |
| **Medical specialty:** | Hematology |
| **Product Code:** | LCP |
| **Device class:** | 2 |
| **Regulation No:** | 864.7470 |
| **Manufacturer:** | Quantimetrix Corporation<br>2005 Manhattan Beach Boulevard<br>Redondo Beach CA 90278<br>Phone: 310/536-0006 FAX: 310/536-9977 |
| **Contact Persons:** | Gebhard Neyer, Ph.D., Director of R&D, 310-536-0006 |
| **Registration No:** | 2020715 |

The Quantimetrix GlycoHemosure is supplied liquid in glass bottles. It consists of human-source blood that was treated to give a stable liquid formulation of two distinct levels of HbA1c.

The HbA1c concentration was determined using an immunoassay method, e.g. Dade HbA1c assay.

The Quantimetrix control material is substantially equivalent to the currently marketed **Lyphochek Diabetes Control** manufactured by **Bio-Rad Laboratories.**

Both feature similar matrices, constituents and stability claims.

**Intended Use**

The Quantimetrix GlycoHemosure is intended for the quality control of laboratory procedures for the quantitation of HbA1c.

**Performance Characteristics**

Accelerated stability studies (25°C and 37°C) and real time studies (2-8°C) were performed to validate the shelf life claim and the opened vial claim of the control material. The results support a shelf life claim (2-8°C) of at least 18 months and an opened vial claim of at least 30 days.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 3 0 2003

Dr. Gebhard Neyer
Director, Research & Development
Quantimetrix Corp
2005 Manhattan Beach Blvd.
Redondo Beach, CA 90278-1205

Re: k032791
Trade/Device Name: GlycoHemosure
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: Class II
Product Code: GGM
Dated: September 1, 2003
Received: September 15, 2003

Dear Dr. Neyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):** K032791

**Device Name:** GlycoHemosure

**Indications For Use:**

The Quantimetrix GlycoHemosure is intended for the quality control of laboratory procedures for the quantitation of HbA1c.

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032791

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** ✓ OR **Over-The-Counter Use** _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)